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Strategic Plan

Biotechnology, Biologics, and Environmental Protection

**Biotechnology Coordination
and Technical Assistance**

Veterinary Biologics

**Veterinary Biologics Field
Operations**

Biotechnology Permits

**Environmental
Documentation**

**United States
Department of
Agriculture**



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Issued December 1989

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Message from the Director

Biotechnology, Biologics and Environmental Protection (BBEP) is faced with the same challenges and opportunities as all of APHIS: an increase in the number of activities within its program area and the growing complexity of those activities. The following strategic plan was developed by BBEP to assist us in meeting the oncoming challenges and opportunities. By careful application of the proposed actions, we expect to be able to fulfill all of our responsibilities and to meet the challenges presented by the changes in science and technology represented in biotechnology, biologics and environmental protection.

To accomplish these goals, we will be concentrating on six strategic issues: management of the externally generated workload, identifying and hiring qualified personnel at all levels within the organization, developing a responsive fiscal and resource management mechanism, maintaining effective relationships with all our collaborators, enhancing the public's understanding of the risks and benefits of biotechnology and biologics, as well as their involvement in environmental protection, and improving support services to facilitate meeting BBEP's goals.

The most important of these is qualified personnel. The sciences associated with biotechnology, biologics, and environmental analysis are dynamic and changing rapidly, requiring expertise that is in short supply. Additionally, the efficient administration of these areas also requires exceptional clerical and support staff. The successful completion of BBEP's mission will require an increased emphasis on hiring and training both technically trained personnel in the scientific fields as well as clerical and support staffs.

BBEP is committed to ensuring that APHIS has the highest standards of professionalism, and that through such professionalism APHIS will continue as a leader in both domestic and international agriculture.

Terry Medley
Director

Mission Statement

Biotechnology, Biologics, and Environmental Protection (BBEP) develops and coordinates policies and procedures, and implements and maintains programs concerning biotechnology, biologics, and environmental protection to fulfill the goals of the Animal and Plant Health Inspection Service (APHIS).

In support of this mission, we:

- Design and manage the environmental analysis process and conduct environmental analyses of Agency proposals and services.
- Design and implement Agency training programs concerning biotechnology, biologics, and environmental protection.
- Design and implement processes to identify emerging issues and develop the necessary regulatory initiatives in the areas of BBEP.
- Provide specialized scientific and technical disciplines and expertise.
- Assure that pure, safe, potent, and effective veterinary biological products are available for the diagnosis, prevention, and treatment of animal diseases through the issuance of licenses and permits and inspecting and monitoring products and facilities.
- Issue veterinary biological permits to exclude the introduction of foreign animal diseases.
- Issue permits for the introduction of genetically engineered organisms. Provide support and advice to ensure that unlicensed veterinary biological products are not shipped within or from the United States and that unauthorized genetically engineered organisms are not introduced.
- Coordinate the development and execution of Departmental and APHIS biotechnology regulatory activities.
- Act as liaison with other Federal agencies, State agencies, and private/public entities on BBEP matters.

We are committed to:

- Providing responsive high quality services.
- Attracting and maintaining a multi-disciplinary, diverse, technically superior, and innovative staff with recognized expertise.
- Establishing and maintaining effective linkages within APHIS.
- Protecting and enhancing the agro-ecosystem and the environment.
- Making decisions consistent with our statutory authority that are impartial, analytical, and scientifically based.
- Utilizing a team approach and recognition of individual accomplishments.
- Cross-utilization of disciplines and personnel within BBEP.
- Equal opportunity in employment and personal and professional growth and development.
- Providing a safe work environment that is conducive to effective job performance.

Critical Strategic Issues

Externally Generated Workload

Issue: The quantity and complexity of the workload in Biotechnology, Biologics, and Environmental Protection (BBEP) is externally driven; however, BBEP must be capable of responding in a timely and credible manner.

Supporting Data:

The number of Licenses, Permits, Environmental Assessments, and other documents issued by BBEP each year is dependent upon the number of applications and requests received. Response to such external requests must be timely. The quantity of work in Veterinary Biologics has more than doubled in the last 7 years as the number of licensed establishments has increased from 46 to 94. Requests for permits for movement or release of genetically engineered organisms have increased at a geometric rate. Requests for permits for release in the first 2 quarters of FY 1989 are already 50 percent ahead and for movement 100 percent ahead of all of FY 1988. Requests for environmental analysis have also increased dramatically. Projections indicate these rates of increase in workload will continue.

The complexity of biologics licensing and staff activities has increased significantly as more applications for genetically engineered products are submitted each year. The complexity of requests for permits to release genetically engineered organisms has also increased as new genetic-engineering procedures are applied. The requirements and standards for environmental analysis and protection that are imposed by outside entities have also made environmental documentation more extensive and complex. Most of these environmental assessments are undertaken for other than BBEP programs.

Biotechnology and environmental concerns have been highlighted by the administration as priority items. BBEP's lead role for the Department in this priority will also effect workload.

Root Causes:

(1) Mandatory requirements for BBEP activities are provided in the Virus-Serum-Toxin Act as amended, the Federal Plant Pest Act, the Plant Quarantine Act, the National Environmental Policy Act, Endangered Species Act, and other related statutes.

(2) The products of genetic engineering technology are just beginning to be presented for release. The number of new biotechnology products presented for licensing and release is predicted to increase at a geometric rate as the potential of this new technology is expanded.

(3) The confidence of academia and the biotech industry in the ability of BBEP to review and issue licenses and permits for regulating genetically engineered products is increasing. This confidence feeds more investment into research and development of new products for consideration.

Conclusions: To respond in a timely and credible manner, BBEP must maintain a highly skilled, flexible, technical staff with diverse scientific skills and maintain a flexible collaborative and dynamic process.

Qualified Personnel

Issue: Identifying, hiring, and retaining qualified personnel for BBEP

Supporting Data:

Utilization and applications of biotechnology to agriculture, including development of agricultural commodities and products such as biologics are expanding much more rapidly than anticipated.

The sciences associated with biotechnology, biologics, and environmental analysis are dynamic and changing, requiring specialized expertise that is in short supply.

Federal agencies are traditionally unable to recruit and maintain top quality personnel for positions where comparable non-Federal wages and benefits far exceed the Federal salary range (e.g. medical, aeronautics, engineering personnel, and legal secretaries). In this regard, the growth of the biotechnology industry has resulted in similar wage and benefit disparities for the types of highly trained and competent scientists and support personnel needed by BBEP, resulting in a lack of competitiveness in hiring.

Root Causes:

(1) Traditional Federal hiring practices have proven inadequate in meeting BBEP's personnel needs.

(2) Innovative hiring practices, including benefits and competitive salaries, adopted by private industry and other Federal agencies, including FDA, NIH, NASA, and EPA, are as yet unavailable to BBEP.

Conclusions: APHIS-BBEP requires specialized expertise.

To meet this specialized need, BBEP needs an efficient mechanism to identify, hire, and retain special disciplines and expertise.

Fiscal and Resource Management Mechanisms

Issue: The need for a resource management system which allows for dynamic expansion and development during this period of exponential growth in BBEP activities.

Supporting Data:

Budgets are based upon single year allotment of funds, and are generated considerably prior to expenditures.

BBEP activities are externally driven and are growing exponentially.

Staff ceilings are based upon past activities and do not reflect current or emerging program needs.

The inability to acquire resources, including personnel, space, and equipment which involve multi-year fiscal planning.

Root Causes:

- (1) Current appropriation and funding system.
- (2) Inadequate long term resource planning.
- (3) Work is predominately generated external to the work place.

Conclusions: BBEP needs a resource management system which will meet its resource needs in the 1990's.

Maintenance of Relationships

Issue: BBEP must maintain effective relationships with Federal agencies, State agencies, and private/public agencies in order to make the best possible informed decisions and enhance voluntary compliance.

Supporting data:

States have enacted legislation in the biotechnology and veterinary biologics area that is contrary to the Animal and Plant Health Inspection Service's (APHIS) policy.

Litigation to enjoin APHIS activities.

Perception of inherent conflicts of interest.

State and local decisions conflicting with APHIS policy and decisions.

Tendency of regulated entities to resist the unfamiliar.

Root Causes:

- (1) Lack of adequate and timely communication.
- (2) Unexplained and inadequately documented decisions, although supported by facts, may be perceived to favor one interest group over another.
- (3) Lack of effective communication systems.
- (4) Lack of sensitivity to the diversity of interested groups.
- (5) Inadequate training in sensitivity when communicating with interested groups.

Conclusions: BBEP must maintain effective relationships and communicate in a fashion that demonstrates that the Agency's decisions are responsive and supported by the facts.

Public Perception

Issue: The public's uncertainty as to the safety, potential risks, and benefits of the environmental release of genetically engineered organisms and the use of the products of biotechnology.

Supporting Data:

Congressional studies questioning the adequacy of the Federal Regulation of Biotechnology.

The extraordinary activity and concerns expressed by special interest groups, and the increased number of FOIA requests.

The challenges and controversy the Agency has experienced with new initiatives in this area.

Root Causes:

- (1) The complexity and dynamic nature of the technology.
- (2) Past unfavorable experiences with new technology, e.g. nuclear power, toxic wastes, etc.
- (3) The Biotechnology community's lack of sensitivity to public concerns and apparent inability to deal with public perception issues.

Conclusions: BBEP needs to work closely with the regulated industry and the public to identify and discuss the public's concerns over biotechnology. This should include an expansion of current BBEP public education efforts and a review of existing APHIS and Departmental public education efforts.

Support Services

Issue: Improve support services to prevent delay or failure in achieving BBEP goals.

Supporting Data:

Lack of prioritizing and review systems to ensure necessary laboratory and enforcement support.

Lack of an established mechanism for acquiring and developing computer software programs to meet specific project needs on a timely basis.

Lack of an established mechanism to ensure that equipment requisitions are processed or are not unreasonably delayed or changed.

Office facilities and equipment are not conducive to efficient production of work.

Changing and unclear policies and procedures for budgetary and personnel actions impede program decisions and implementation.

Lack of information on procedures for training and maintaining the expertise of employees prevents continued development.

Root Causes:

- (1) There is no formal procedure or lines of communication for providing that groups responsible for support services are accountable for services provided.
- (2) There is a lack of a formal procedure for prioritizing support services.

Conclusions: BBEP needs to work with support service groups to streamline, coordinate, explain, and communicate its needs, or, alternatively, provide for its own support.

Strategy Statement

The BBEP strategy is to ensure that its resources, including employees, processes, systems, equipment, are capable of developing and delivering the high quality services required to fulfill APHIS responsibilities in the highly technical and dynamic fields of biotechnology, biologics, and environmental protection.

Important elements of the strategy are to:

- Identify, hire, retain, and maintain qualified technically trained personnel.
- Establish a continuous, collaborative, and analytical process to effectively identify and evaluate existing and emerging needs and program delivery.
- Establish and maintain effective communications with State and Federal Government and public/private entities.
- Identify and obtain the resources, including processes, systems and equipment, which are necessary to conduct our activities.
- Explore and assess alternative and innovative methods to achieve program goals.

Through this strategy, BBEP will continue to enhance and expand its capability to enable APHIS to provide high quality services and to meet the existing and emerging needs of U.S. agriculture and the American people.

Long-Range Goals

1. By June 1991, have in place a flexible, collaborative, and dynamic process to respond to an externally generated workload in a timely and credible manner.
2. By March 1990, develop and adopt a plan to ensure that BBEP has the capability to identify, hire, and retain qualified personnel.
3. By March 1991, have in place a resource management system which will meet BBEP resource needs in the 1990's.
4. By September 1991, identify interest groups, stakeholders, and cooperators that have an interest in BBEP programs and issues; determine the issues and area about which they are concerned; and have developed and carried out effective on-going means of communications to these groups on these issues.
5. By December 1992, establish a system to inform, educate, and counsel different sectors of the public as to the responsibilities, operation, and activities of BBEP.
6. By September 1991, develop and adopt a formal procedure to evaluate and provide feedback on the responsiveness of support service groups to Biotechnology, Biologics, and Environmental Protection needs.

Biotechnology, Biologics, and Environmental Protection Multiyear Action Plan 1

Goal Statement: By June 1991, have in place a flexible, collaborative, and dynamic process to respond to an externally generated workload in a timely and credible manner.

Action Steps	Feedback/Products	Units	Target Dates	Additional Resource Needs
1. Submissions				
(a) Develop an action plan to improve the quality and timeliness of submissions to BBEP for licenses, permits, and environmental analysis.	Plan	BBEP	Dec. 1989	No
(1) Prepare a user's guide with complete up-to-date S.O.P.'s for the preparation of submissions to BBEP staffs.	User's guide	BBEP VB	Apr. 1990 Jun. 1991	Yes
(2) Develop a training process for public and private personnel on how to prepare submissions for licenses, permits, and environmental analysis.	Plan	BBEP	Apr. 1990	Yes
(b) Develop an action plan to identify and quantify projected external workload.	Plan	BBEP	Sep. 1990	No
(1) Develop a data collection system for anticipating workload considering economic, technological, social, and statutory changes.	System	BBEP		No

2. Procedures

(a) Maintain an ongoing process to determine where operational procedures may be streamlined to handle submissions more efficiently yet maintain proper checks and balances.	Operations flow charts	BBEP	Mar. 1990	No
(1) Develop written S.O.P books for staff operations to assure uniformity in application and also serve as a guide for new employees.	Written S.O.P.'s	BBEP	Jun. 1991	Yes
(2) Utilize new technology to improve communications and efficiency wherever indicated.	Annual report and recommendations to Director	BBEP	Jan. 1991	Yes

3. Cross Utilization of Personnel

(a) Assure adequate cross training and backups for each staff position to assure continuity with leave absences, reassignments, resignations, or retirements.	Recommendations to Director	BBEP	Ongoing	No
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Biotechnology, Biologics, and Environmental Protection
Multiyear Action Plan 2

Goal Statement: By March 1990, develop and adopt a plan to ensure that BBEP has the capability to identify, hire, and retain qualified personnel.

Action Steps	Feedback/Products	Units	Target Dates	Additional Resource Needs
1. Review organizational structure in each BBEP unit to assure proper ratio of support to scientific staff and to identify all personnel needs.	Reports for BBEP TMT response and action	All BBEP units, coordinated with Director's Office	Begin Oct. 1989	No
2. Review existing BBEP hiring procedures in conjunction with M&B and R&D procedures.	Reports for BBEP response and action	BBEP, M&B, R&D	Begin Oct. 1989	No
3. Develop action plans to address deficiencies identified in existing BBEP hiring procedures, and recommendations on Agency procedures.	Action plan report and recommendations	All BBEP, and appropriate units	Begin Oct. 1989	No
4. Increase BBEP resources devoted to training of technical specialists, and increase use of innovative hiring practices.	Budget additional funds for hiring and training	All BBEP units, coordinated through Director's Office	Begin Apr. 1990	Yes
5. Develop, and adopt, a plan for recruitment based upon recognition of specific needs and skills required within BBEP, formal training, cooperative programs, educational exchanges and IPA.	Hiring and retention plan	All BBEP units, coordinated through Director's Office, with appropriate M&B, and R&D units.	Begin Jan. 1990	Yes

Biotechnology, Biologics, and Environmental Protection
Multiyear Action Plan 3

Goal Statement: By March 1991, have in place a resource management system which will meet BBEP resource needs in the 1990's.

Action Steps	Feedback/Products	Units	Target Dates	Additional Resource Needs
1. Identify trends, mechanisms, and formulas for predictive resource use.	Est. of BBEP management team	BBEP	Nov. 1989	No
2. Identify sources of information on fiscal and resource tracking within BBEP unit.	Tabulated resource management data	BBEP, ISCD, M&B	Mar. 1990	Yes
3. Analyze fiscal/resource data to identify trends, mechanisms, and formulas for predictive resource use.	Resource management/ planning report	BBEP, BAD	Sep. 1990	Yes
4. Predict resource needs and allocations	FY 1991 resource management analysis, FY 1992 BBEP budget plans	BBEP, Resource Management Group	Mar. 1991	Yes

Biotechnology, Biologics, and Environmental Protection
Multiyear Action Plan 4

Goal Statement: By September 1991, identify interest groups, stakeholders, and cooperators that have an interest in Biotechnology, Biologics, and Environmental Protection (BBEP) programs and issues; determine the issues and area about which they are concerned; and have developed and carried out effective on-going means of two-way communications to these groups on these issues.

Action Steps	Feedback/Products	Units	Target Dates	Additional Resource Needs
1. Develop a procedure for identifying internal and external interest groups, stakeholders and cooperators.	Survey; report; list	All BBEP units	Jan. 1990	No
2. Determine emerging issues/needs of concern to these various internal and external groups.	Survey; report; list	All BBEP units	Mar. 1990	No
3. Evaluate significance and prioritize the identified needs/issues by the Director/Deputy Directors	Prioritized list of emerging needs/issues	All BBEP units	Mar. 1990	No
4. Develop an issue management system	Issue management system	All BBEP units	Oct. 1990	No
5. Enter selected significant needs/issues into the issue management process	Appropriate program response/position	BCTA	Jan. 1991	No
6. Develop and implement a communications plan	BBEP communications plan presented to Director for approval or position to interested group	Appropriate units of BBEP/LPA	Apr. 1991	Yes
7. Evaluate cooperative relationships and programs	Evaluation reports	BBEP/PPD	Jul. 1991 Ongoing	Yes

Biotechnology, Biologics, and Environmental Protection
Multiyear Action Plan 5

Goal Statement: By December 1992, establish a system to inform, educate, and counsel different sectors of the public as to the responsibilities, operation and activities of BBEP.

Action Steps	Feedback/Products	Units	Target Dates	Additional Resource Needs
1. Review of current and past BBEP public education efforts.	Report	BBEP, R&D, S&T, LPA	Jul. 1990	No
2. Develop and analyze all possible methods of public information available to USDA, and APHIS.	Reports and recommendations	BBEP, LPA	Sep. 1990	No
3. Begin expanded development of public education/information effort.	Presentations, personnel needs identified, displays, manuals	BBEP, S&T, LPA, R&D	Mar. 1991	Yes
4. Review and evaluate year's public relations/education effort and plan for next.	Review and report	BBEP, LPA, PPD	Dec. 1992	Yes

Biotechnology, Biologics, and Environmental Protection
Multiyear Action Plan 6

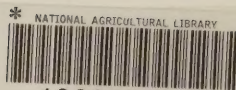
Goal Statement: By September 1991, develop and adopt a formal procedure to evaluate and provide feedback on the responsiveness of support service groups to Biotechnology, Biologics, and Environmental Protection needs.

Action Steps	Feedback/Products	Units	Target Dates	Additional Resource Needs
1. Identify critical support services needed by BBEP and the units responsible for providing them.	List of critical support services.	BBEP	May 1990	No
2. Determine existing procedures for obtaining support services for BBEP.	Report on how to meet support service needs.	BBEP, maybe others	May 1990	No
3. Examine issues involved in support service delivery to BBEP.	Recommendations on issue resolution.	BBEP	Jan. 1991	No
4. Develop a formal procedure that prioritizes and communicates BBEP support service needs.	Adoption of a procedure	BBEP	Sep. 1991	No

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